



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/465,491      | 12/16/1999  | Sheng-Yung Pai Chang | RPA1002             | 8931             |

22829 7590 02/12/2003

ROCHE MOLECULAR SYSTEMS INC  
PATENT LAW DEPARTMENT  
1145 ATLANTIC AVENUE  
ALAMEDA, CA 94501

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/12/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/465,491

Applicant(s)

CHANG ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Janaruy 23, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 23 January 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.

Claim(s) objected to: NONE.

Claim(s) rejected: 21, 28-33 and 35-49.

Claim(s) withdrawn from consideration: NONE.


8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE:

Newly Added Claims 50-53 are directed to methods for identifying the presence of cancerous cells in a human sample by determining the quantity of hTERT by amplifying the B-region of the hTERT gene. As previously pointed out in the final rejection, the specification describes amplifying hTERT with a primer that hybridizes within exon 8 and a primer that hybridizes either upstream of exon 7 or downstream of exon 8. This teaching does not support a pair of primers which hybridizes upstream and downstream of exon 8 (as required by Claim 51 and 5). The specification clearly states that the "a method of quantitating hTERT mRNA expression by amplifying as above (using primers of SEQ ID NO: 2 and 3; exon 6 and exon 9) and then selectively measuring only the amount of product generated from the full-length mRNA would provide an unreliable measure of the mRNA which encodes an active hTERT protein. This unpredictability can be eliminated by selectively amplifying only hTERT mRNA that encodes an active hTERT protein, as described in the following examples." (pages 22-23).

Newly Added Claims 50-53 raise the issue of art rejections which would require further consideration and/or search.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment and response asserts that Claims 50-53 are described by the specification. While this assertion is factually correct, the specification clearly teaches that the primers provide unreliable results for the hTERT quantitation. The invention is directed to overcoming this unreliability with unexpected results of placing the primers in exon 8 and the other primer either upstream or downstream. .

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600